

Office of Special Nutritionals (HFS-450) Center for Food Safety and Applied Nutrition U.S. Food and Drug Administration 200 C Street, S.W. Washington, D.C. 20204

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| AUG 2 7 2001 | |
| BY: | - |

Re: Label claims made for nutritional product

August 23, 2001

Ladies/Gentleman:

This letter notifies the Food and Drug Administration that within the past 180 days our company has begun to market Omega Complete $^{\text{TM}}$ [Dietary] Supplement, with the following statement of nutritional support included on the label and in labeling for the product:

"Omega Complete™ helps maintain healthy cardiovascular and immune systems. It also helps support joint, eye, and skin health as well as hormone balance and brain growth and function."

The dietary ingredients of the product that are the subject of the above statement are: omega-3 fatty acids (eicosapentaenoic acid and docosahexaenoic acid), omega-6 fatty acids (gamma linolenic acid), and omega-9 fatty acids.

It is hereby certified that the information in this notification is complete and accurate, and that our company has substantiation that the above statement is truthful and not misleading.

Very truly yours,

Body Wise International Juliana Tinkelenberg Director of Communications

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